

REMARKS

By this amendment, claims 8 and 11 have been amended; claims 1-7 have been withdrawn from consideration by the Office. These amendments are made to even more clearly recite the claimed invention, do not add prohibited new matter, and are fully supported by the specification. Reconsideration and withdrawal of the rejections set forth in the outstanding Office Action are respectfully requested in view of the foregoing amendments and the following remarks.

**Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

The Office Action rejects claims 8-14 under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential steps. Specifically, the Examiner alleges that a step for obtaining samples and a determination step to “achieve the purpose stated in the preamble” are essential steps. Applicants respectfully disagree.

Section 2172.01 of the MPEP indicates that a 112 rejection for omitted steps is appropriate where “[a] claim which omits matter *disclosed to be essential to the invention as described in the specification or in other statements of record* may be rejected under 35 U.S.C. 112, first paragraph.” Furthermore, § 2172.01 requires claims to recite elements and steps that are “*necessary* to practice the invention.” However, neither the specification nor any other part of the record indicates that “obtaining samples” would be an essential step of the invention. Furthermore, Applicants submit that it is not necessary that one skilled in the art “obtain samples” to practice the claimed invention, as there may be embodiments of the invention that do not necessarily require this step.

As for the Examiner's arguments regarding "determination steps," Applicants disagree that such steps are necessary because they are already recited in the preamble of the claims. However, without agreeing with or acquiescing to the rejection, Applicants note that the claims have been amended; claim 8 recites "wherein the presence of the mutant Plk protein indicates an increased likelihood of malignancy." For at least the reasons provided above, Applicants respectfully request that the rejection be withdrawn.

### **Claim Rejections – 35 U.S.C. § 112, First Paragraph**

The Office Action rejects claims 8-14 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirements. Specifically, the Office Action alleges that the claims encompass a method for detecting mutant Plk protein in all types of cells, and the Examiner asserts that not all cells have mutant Plk proteins. Without agreeing with or acquiescing to the rejection, Applicants note that the claims have been amended to recite "detecting presence of the mutant Plk nucleotide sequence encoding a mutant Plk protein in a cell in which the wild type cell expresses a wild type Plk protein."

Furthermore, the Office Action asserts that the specification does not establish that the claimed method can verify the presence of malignant tumors, or the link between mutant Plk protein and diagnosing malignant tumor cells. Without agreeing with or acquiescing to the rejection, Applicants note that claims 8 and 11 have been amended; claim 8 recites "[a] method of cell analysis for determining an increased likelihood of malignancy" and "wherein the presence of the mutant Plk protein indicates an increased likelihood of malignancy."

Lastly, the Examiner asserts that the specification does not teach that low levels of Plk expression lead to malignant tumors. Under MPEP § 2164.05, to overcome an enablement rejection, Applicants must present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973). Furthermore, MPEP § 2164.05 indicates that the evidence provided by applicant need **not be conclusive** but merely **convincing** to one skilled in the art.


Applicants note that independent claims 8 and 11 recite “an increased likelihood of malignancy” and “an increased likelihood of the presence of malignant tumor cells,” respectively. The specification and the experimental results provided therein support this conclusion by demonstrating that Plk mutations are associated with low expression levels of Plk protein (see, e.g., page 13, paragraph 2, of the specification). On page 13 of the specification, Applicants note that “it has been suggested that the loss of function or low expression levels of the checkpoint genes may contribute to tumorigenesis in human cancer.” Figure 1a demonstrates that low levels of Plk protein have been observed in solid cancer cell lines A431, Hep G2, A549, and MKN74 (*see also* page 13, paragraph 1, of the specification). Applicants then investigated the correlation between low expression levels of Plk protein and Plk protein mutations, and discovered that Plk harbors mutations in the solid cancer cell lines A431, Hep G2, A549, and MKN74, as shown in Table 1. Accordingly, Applicants submit that the specification and experimental results would easily convince one skilled in the art that Plk mutations are correlated with “an increased likelihood of malignancy.” Thus, the specification enables one skilled in the art to make and use the claimed invention using the application as a guide without undue experimentation.

Accordingly, Applicants submit that the specification has satisfied the enablement requirements. Applicants respectfully request reconsideration and withdrawal of the outstanding rejection, and an indication of the allowability of all claims pending in the present application in due course.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If the Examiner has any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
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